UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 11

UNITED STATES DEPARTMENT OF LABOR
Occupational Safety and Health Administration

MARY MADISON,	)	
	)	
	)	
	)	
Complainant	)	
V.	)	
	)	No. 301015087
Creative Werks, LLC	)	
a Delaware Limited Liability Company	)	
	)	
Respondent.	)	

DECLARATION OF MARY MADISON

Mary Madison, for her declaration, pursuant to 28 U.S.C. §1746, states as follows:

I am over twenty-one years of age and am competent to testify to the matters set forth in this

Declaration. The facts stated herein are within my personal knowledge and are true and correct.

I was offered a job as the Quality Regulatory Manager at Creative Werks Elk Grove facility on September 20, 2022. My compensation was 95,000.00 dollars per year, plus 10% bonus and a sign on bonus of $2,500.00. See Exhibit 1

The job description referenced in Creative Werks rebuttal to my complaint is for a Regulatory Specialist and therefore is not applicable to me. See Respondent's Exhibit1

I began working on September 27, 2022 at Creative Werks as the Quality Regulatory Manager.

The responsibilities entailed compliance with the Food Safety Modernization Act "hereinafter referred to as FSMA[1]" and other regulatory schemes such as the Bioterrorism Act of 2002 (Food Defense) in addition to being a liaison between customers and the company regarding compliance quality, regulatory and customer requirements (See Exhibit 2 FDA report pg. 8)

[1] FSMA amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

On September 27, 2022, I was instructed to report to Creative Werks' Bartlett facility on September 28, 2022 because the FDA was coming to the facility.

DAY ONE OF THE FDA VISIT CONSUMER COMPLAINT REVIEW

After reporting to the facility on September 28, 2022 and while waiting for the FDA inspector Erich Zicher began making disparaging and belittling remarks about the FDA inspector; including but not limited to her effectiveness and abilities as an FDA inspector. Mr. Zicher's remarks along the lines of "she is stupid, she does not know anything etc. He further demeaned her for referencing inadequacies that made it seem that he was incompetent or stupid in the report that she had previously written in July of 2022 relative to the Elk Grove facility. He spent a significant amount of time complaining about her and disparaging her.

Mr. Zicher also spoke at length about his past history as a golf pro and being a music major.

Upon the inspector's arrival at approximately 2:12 pm, she stated that she was there in reference to a customer complaint. She remarked that she was able to gain access into the facility without being properly vetted (See Exhibit 2 pg. 16 § Food Defense) Moreover, the inspector stated that the facility had not been inspected previously because it was not properly registered with the FDA.

The attendees on behalf of Creative Werks were Mr. Erich Zicher, Ms. Angela Knabe, Anupam Sharma and myself, we introduced ourselves to the inspector. Mr. Zicher identified himself as the person most in charge. Subsequently, the inspector issues a notice of inspection--FDA form 482 to Mr. Zicher. We were instructed by the FDA inspector to provide any evidence of being a Preventive Control Qualified Individual, ("hereinafter PCQI"). Mr. Zicher, Ms. Knabe and I provided that information to the inspector.

The inspector began to conduct her interview indicating that there was a consumer complaint made in October of 2021 regarding a Cheetos product that she wanted to discuss (See Exhibit 3). In response, Mr. Zicher refused to produce documents relative to the complaint without permission from the client (See Exhibit 2 pg. 15 § Refusal). He further indicated that he was not aware of a complaint in October of 2021, but was aware of a complaint in May in 2021 regarding a Pepsi Cheeto product (See Exhibit 4 pg. 4). Mr. Zicher indicated that they were aware of a non-conformity relative to burnt seals. He also indicated that they had conducted an investigation, but further indicated that this was no longer an issue, as Creative Werks was no longer doing business with Pepsi (See Exhibit 2 pg. 4 ¶5). There was a somewhat heated discussion between Mr. Zicher and the inspector regarding the timing and length of the investigation.

During the relevant time, Mr. Zicher did not offer any tangible evidence or any particulars on the investigation or any subsequent remedial measures taken to mitigate the non-conformance and to prohibit adulterated food from entering the stream of commerce.

The inspector left at approximately 4:30 pm and indicated that she would return on the next day, Thursday, September 29, 2022.

Mr. Zicher continued to disparage the FDA inspector's competency. He also stated that the production and tendering of documents is not permitted and if we have to produce documents, we are only to show them electronically.

DAY TWO OF THE FDA VISIT SITE INSPECTION

The FDA inspector returned on Thursday, September 29, 2022 at approximately 1:00 pm. The inspector reviewed the consumer complaint from the previous day continuing to make inquiries about the timing and resolution of the complaint. Mr. Zicher again denied having any knowledge of the October 2021 complaint.

The inspector moved on and began doing an audit inspection of the company's records and relevant practices. Mr. Zicher was not initially compliant with the request; refusing to produce the requested information, but ultimately acquiesced.

The inspector asked about training. Various types of training were identified, including 5S training. The inspector asked what that was and no one could speak to what that was including Mr. Zicher.

The inspector indicated that she wanted to tour the facility. Of course, I wanted to accompany them because I was new and I wanted to see the facility. Mr. Zicher stated that if I was accompanying them on the facility tour my jewelry needed to be removed. He indicated to me that I had a dress on. However, Ms. Knabe stated that I was all right to go, indicating that the company policy stated that one's extremities were to be covered. There was no exposed flesh; my arms and legs were fully covered.

To minimize the discussion, I informed him that I had pants in the car and that I would change.

I was unable to remove one of my screwed-in stud earrings. Per the FDA, jewelry is permissible if it is secured. Further the rule is geared towards those that come in direct contact with food, food-contact surfaces, and food-packaging materials (See 21 CFR Subpart B § 117.10 (b)(4)). By Mr. Zicher's own admission in his declaration, I could not get the earring out. Moreover, he neglected to state that head covers were used that also covered the ears that could have caught

and restrained any particulate from being introduced in the manufacturing facility; therefore, controlling and minimizing any risk.

I did not pose any safety risk, as I was not going to be working on a line or coming into direct contact with any product, surface or packaging material. Thus, it would have been highly unlikely or improbable that any contamination would have occurred.

I contend that any embellishments from my prescription eyeglasses would not have posed a risk for the same reasons.[2] Additionally, the use of goggles could restrain any particulate from being introduced into the manufacturing facility.

I do not paint my fingernails. Mr. Zicher's statement that my nails were painted is patently false.

Further, I contend that my presence during the inspection was not essential, as I had just started and had not been to the facility before. I had no knowledge about the facility and its operation. Additionally, the person that I was replacing, Ms. Knabe did not accompany them either nor was she invited or required to go on the tour.

Ms. Knabe and I remained in the conference room further suggesting that it was not as crucial as Mr. Zicher is now attempting to make the issue to be.

Upon their return from the tour, it was revealed that the FDA inspector had observed improper sanitation being performed.

Another issue arose when the inspector wanted to take sample labels off the line that was running. Initially Mr. Zicher refused and told the inspector that those labels did not belong to Creative Werks, but their customer, Hersey. Mr. Zicher also indicated that they needed permission from the customer to do so.

Ms. Knabe reached out to Teddy Cadet, the Senior QRC Specialist, from Hersey asking for permission to provide the FDA the labels. Mr. Cadet indicated that it was ok to give them the labels, as they were entitled to these materials during an inspection (See Exhibit 5).

There were five (5) observational findings identified by the FDA inspector at the closing meeting on September 29, 2022. These findings ranged from improper record keeping to sanitation and pest control issues.

[2] Further, even knowing that an inspection was going to take place, there is nothing that could have been done to replace my eyeglasses on such short notice.

The other attendees were perplexed that the inspector raised an issue about the records not being properly kept. Specifically, the records were not dated. No one seemed to know or understand the relevance or importance of the issue raised.

Subsequently, that evening, Mr. Cadet followed up asking what was the reason for the FDA visit.

In response, Mr. Zicher sent out an email entitled "FDA Inspection Routine Inspection" at 9:38 pm on Thursday, September 29, 2022. In it, Mr. Zicher discussed the Pepsi consumer complaint along with identifying the five (5) observations made by the FDA Inspector (See Exhibit 4).

In sum, on September 28 and 29, 2022, I engaged in protected activity[3] when I participated in a FDA audit/inspection that resulted from a consumer complaint at Creative Werks Bartlett facility.

FOLLOW UP AFTER AND DEBRIEF OF THE FDA VISIT

On Friday, September 30, 2022, Mr. Zicher solicited input from myself, Ms. Knabe and others on how to couch the FDA visit to craft his response and inform other clients of the FDA visit.

On September 30, 2022, I began performing a Root Cause Analysis of the deficiencies identified in the closing meeting with the FDA.

In performing the Root Cause Analysis of the findings, I observed that there were a number of issues of non-compliance with FSMA and the Bioterrorism Act of 2002.

I engaged in protected activity when I spoke with Mr. Steve Schroeder on Friday, September 30, 2022 regarding the FDA inspection while at the espresso machine. He asked me about the inspection and in particular about what happened with the Pepsi complaint. I indicated that it was an issue relative to the timing of the complaints and investigation. I also indicated that the requests from the FDA inspector were not unreasonable and that documents were not produced to the FDA as requested. Mr. Schroeder stated that he "wanted to change the culture to be more transparent." He also stated that "he hoped that I could be of help to the company."

I further indicated that I was in the process of drafting correspondence to help clarify the requests and findings of the FDA inspector during the visit. Mr. Schroeder told me that he had sent some questions to Mr. Zicher regarding the FDA visit and he asked me to ask Mr. Zicher to share the questions that he sent him with me so that I could respond to them.

[3] As defined by 21 U.S.C. § 399d (a)(1)

As promised, later that afternoon, on Friday, September 30, 2022, I presented for review the corresponding rules, regulations and statutes that underscored the requests and observations made by the FDA inspector to identify and shore up any outstanding gaps for compliance (See Exhibit 4 pg. 1).

During the relevant time, I had no idea that a number of documents requested did not exist. Nor did I understand that documents that did exist did not meet the requirements of 21 CFR 117 and the food defense under the Bioterrorism Act of 2002.

REMEDIATION OF OUTSTANDING NESTLÉ AUDIT DEFICIENCIES

In attempting to remediate outstanding customer audit findings from July of 2022, I discovered that the food safety plans were either inadequate or did not exist in contravention of 21 CFR 117 and other food defense requirements under the Bioterrorism Act of 2002. Additionally, I also discovered that Creative Works had repeated non-conforming audit findings that still had not been mitigated or remediated.

For example, it is a documented fact that Creative Werks only had four (4) food safety plans. Plans that were based on Hazard Analysis Critical Control Points, "hereinafter HACCP[4]." This is contravention of 21 CFR 117.126. Further, none of the required plans were developed for Nestlé.

HACCP is the internationally recognized standard that was the forerunner and the precursor to Hazard Analysis and Preventive Control, "hereinafter HARPC." HARPC became the standard in the United States when the Preventive Control for Human Food, "hereinafter PCHF" rule became final in September 2015. PCHF rule requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards. (FDA https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food)

HARPC-The Preventive control systems emphasize prevention of hazards before they occur rather than their detection after they occur. [5]

Creative Werks is a registered facility under the Bioterrorism Act of 2002, which subjects Creative Werks to the FDA's PCHF rule.

[4] The FDA defines HACCP as a "management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product" (FDA 02/25/2022).

[5] Sherod, Anne (11 May 2015). "The ABCs Of Building A Food Safety Plan: From HACCP To HARPC". *foodonline.com*. Archived from the original on 14 December 2018. Retrieved 2 August 2023.

In reviewing Creative Werks records during that relevant period there was no evidence that Creative Werks had ever had PCHF compliance using the HARPC standard.

The FDA clearly states that: "This hazard analysis must be written, regardless of whether any hazards requiring a preventive control are identified." (FDA-Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry § 1.2 ¶ 2).

The FDA Guidance documents represent the "FDA's current thinking on a topic or FDA's interpretation of our policy on a regulatory issue" (FDA 2023).

Further, a plan is required even if it is the same product being run at a different facility See 21 CFR 117; Also, see FDA Frequently asked questions on PCHF. https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma

I communicated to Mr. Zicher these deficiencies and our non-compliance that underscored the audit deficiencies. I was told by Mr. Zicher on several occasions that Donna Bjurlin, from Nestlé, was being picky and that he was not inclined to make any changes (See Exhibit 6). I was also instructed by Mr. Zicher not to reference the regulations and standards when corresponding with Donna on behalf of Nestlé.

MEDFAST POTENTIAL NEW CUSTOMER-BENSENVILLE

On October 3, 2022, I met Mr. Zicher at yet another Creative Werks facility in Bensenville to meet with a potential new customer Medfast.

While we were waiting for the potential clients, Mr. Zicher and I discussed the FDA audit/inspection. We discussed the complaint. We also discussed how it seemed that Creative Werks was unaware that it had non-conforming/adulterated product that it should have been aware of since May of 2021 and did nothing to prevent it from entering into the stream of commerce for human consumption. I shared with him that a good starting point was to understand what standards we needed to comply with based upon our operations. I also shared with Mr. Zicher that Mr. Schroeder wanted him to share with me the questions that Mr. Schroeder had sent to him regarding the FDA visit on September 28-29, 2022.

Mr. Zicher indicated that I did not understand the culture there and that he would not be providing me with the information Mr. Schroeder asked me to ask him to share with me. He also indicated that he and Ron Sammeth, the COO, decided what Mr. Schroeder should see and know.

Later during the Medfast visit, several questions were raised by them relative to basic requisites under FSMA relative to likelihood/severity of occurrences for hazards related to their product. For example, the issue arose as to whether Creative Werks performed environmental monitoring. The question was posed after Medfast representatives saw the storage of large amounts of corrugated boxes in the warehouse. The warehouse presented conditions that supported optimal growth for mold and other microbes. This is a reasonable and foreseeable hazard that could have been easily identified and managed from the proper execution of a science risk based hazard analysis.

BLUE DIAMOND GROWERS AUDIT-BENSENVILLE

On the next day, October 4, 2022, I began preparing for an upcoming audit that I was tasked to facilitate on October 6, 2022 on behalf of Blue Diamond Growers "hereinafter BDG." BDG had sent over an audit plan of specific items that they wanted to review during the audit (See Exhibit 7).

In my preparation for the BDG audit, I found a number of deficiencies and in an attempt to remediate them prior to the audit, I informed Mr. Zicher of these deficiencies (See Exhibit 8).

I was told by Mr. Zicher not to worry about the deficiencies because in his experience "no one reads the documents" and to "use whatever documents we have."

I was instructed by Eric Zicher, Director of Food Safety to provide false, inaccurate and misleading information to clients after I specifically pointed out deficiencies in the documentation.

On October 6, 2022, the auditor, Keira Kaur Dhillon came to perform the audit. We began our introductions; Ms. Dhillon went first indicating that one of her previous employers was Kraft Foods. I went next and Mr. Zicher went last. Mr. Zicher told Ms. Dhillon that they had something in common because they both had worked at Kraft. She in turn asked him who was the CEO when he worked at Kraft? Mr. Zicher did not and could not answer her question--The room was filled with silence.

Seemingly to deflect the awkward situation, Mr. Zicher made remarks poking fun at me to Ms. Dhillon that I had all these tabs open on my computer relative to the documents that they had requested to review.

I responded to the effect that since they were kind enough to send over a comprehensive list of what they wanted to review during the audit and in the interest of everyone's time, it seemed prudent to be prepared and not to have to search for documents (See Exhibit 7).

The auditor remarked that the audit exhibited readiness because of the readily available documents (See Exhibit 9).

Unfortunately, there was an issue identified by the auditor in one of the documents she reviewed that could have been identified and remediated. This was not the case because I was instructed to ignore the deficiencies identified (See Exhibit 8).

FOLLOWING UP ON UNREMEDIATED OUTSTANDING NESTLÉ AUDIT ISSUES

In an effort to follow up on the outstanding audit non-compliances relative to Nestlé that had been due and owing since July of 2022, I again broached the outstanding issues from the audit along with conversations[6] that I had with Donna Bjurlin from Nestlé Corporate Quality with Mr. Zicher. Mr. Zicher stated that "her expectations were not realistic and that she was being picky."

After closer examination of the nonconformities, Creative Werks documentation, Nestlé requirements and the regulations, I discovered that her requests were directly tied to documents, procedures and analyses that would have resulted from a proper Food Safety Plan and other scientific risk based requisite and prerequisite programs, such as science risk based hazard analysis, Good Manufacturing Practices, ("hereinafter GMPs"), allergen controls, supply chain management, and Integrated Pest Management among other programs.[7]

For example, the Nestlé audit noted that Creative Werks failed to properly vet or produce evidence of proper receiving of products, even though it may have come from them initially (See Nestlé audit Exhibit 10).

To demonstrate that this was a common practice of not exercising proper food safety/defense, Mr. Zicher instructed me to not follow various requirements because the product was coming from Mondelez (See Exhibit 11).

Supplier verification is a requisite relative to food safety/defense. Further, Creative Werks purchased commodities from its clients that it packaged for sale and had a duty to ensure that food was safe and not adulterated before allowing it to be introduced into the stream of commerce for human consumption. Further, a Foreign Supplier Verification Program, ("hereinafter FSVP"), would be required when purchasing commodities outside of the United States for resale in the United States (See 21 CFR Subpart G).

[6] A longstanding biweekly meeting was held by Nestlé to address the outstanding audit deficiencies.
[7] The lack of a proper pest management program was evidenced by one (1) of the observations made by the FDA inspector on September 29, 2022 that noted there were pest control issues at both the Elk Grove and Bartlett facilities (See Exhibit 2 pg. 16 cross reference FDA July 2022 EIR 3010131930). The same observations were noted for sanitation and record keeping.

There was no adequate mechanism in place nor did Creative Werks consistently follow whatever procedures it had in place relative to supplier verification (See Exhibit 12). Additionally, I had been instructed to release material that was being held for non-conformance based on this same premise on several other occasions.

TRACEGAINS DOCUMENT REQUESTS

I began reviewing TraceGains[8] requests for documents and searching for the requested documents from numerous clients. It was during this process that I began to fully understand that there were no specific documents relative to each client and their respective products. For example, one client was looking for a recall plan among other things. The only recall plan was for General Mills. The client was not General Mills (See Exhibit 13).

There were TraceGains requests dating back to 2021. These requests were not able to be fulfilled because of the lack of proper food safety plans, as well as compliance with customer requirements, prerequisite and requisite programs among other metrics. These requests mirror the audit deficiencies identified in the Nestlé audit.

Mr. Zicher makes a patently false and misleading statement in his declaration that the TraceGains requests at issue of almost 150 requests were a result of ongoing requests from a previous customer that no longer did business with Creative Werks (See Exhibit 14 pg.1).

The requests were made from various clients that were actively doing business with Creative Werks. Another example is Wilton Brands. Wilton Brands began requesting documents in 2021 and in October of 2022 began actively seeking these documents demanding to know why these documents were not being provided (See Exhibit 14 pg. 2)

The common practice had been recycling documents between customers to meet whatever requests, leading customers to believe that the documents provided to them by Creative Werks were inherent to their particular operation; when in fact they were not.

Customers relied on the information provided by Creative Werks for their business records and to demonstrate compliance with the FFDCA (FSMA) and relevant regulations as applied to food safety. For example, Nestlé was confronted with a compliance audit and had unmet past due deadlines of several months for outstanding audit deficiencies. I was contacted by Nestlé to provide updates and reasonable remediation steps. I reached out to Mr. Zicher and when he finally responded, he ignored issues that were a direct outgrowth or part of the mandated Food

[8] TraceGains is an online exchange platform for requesting, sending and receiving documents across the supply chain.

Safety Plans and other matrices or with non-relevant and noncompliant responses (See Exhibit 6).

Further, I emailed Mr. Zicher about the voluminous document requests. I also told him I was uncomfortable with providing any false and misleading information to the customer based upon him previously instructing me to do so. TraceGains sent out weekly status alert relative to documentation request. Mr. Zicher was fully aware of the situation. Mr. Zicher once again has made patently false and misleading statements (See Exhibit 14).

FOOD SAFETY PLANS

I repeatedly asked Mr. Zicher about the Food Safety Plans and how they were constructed and what scientific basis was used. Finally, Mr. Zicher indicated that he used the Food Safety Preventive Control Alliance public draft edition participant manual that he received during training while working at Kraft as the basis for drafting the plan in addition to excerpts from the FDA template (See Exhibit 15).

None of these referenced documents supported how he derived the information referenced in his plan. There were also fundamental deficiencies with the document such as it being undated[9]. Even using the incorrect standard of HACCP, the application of the HACCP principles were still incorrect, as the severity/likelihood matrix did not support the information contained on the HACCP plan.

Mr. Zicher could not tell me the science, the method or point to any analysis to justify what was contained in the food safety plan he drafted relative to Dunkaroos that was to be the template for any other food safety plan (See Exhibit 15).

I explained to Mr. Zicher that such a plan was a cross-functional[10] document supported by process owners and other contributors founded on scientific principles such as Standard Operating Procedures[11] based upon scientific and standardized test methods and other fundamental principles, etc.

Creative Works also lacked change control management an essential function ensuring that various requirements are being met to remain compliant with FSMA and other relevant statutes. Further, change management is directly correlated to preventive controls such as validation,

[9] Undated documents are in contravention of the record keeping requirements of 21 CFR 117.301.

[10] Cross-functional is defined as denoting or relating to a system whereby people from different areas of an organization work together as a team. Cambridge Dictionary https://dictionary.cambridge.org/us/dictionary/english/cross-functional.

[11] Creative Works did not have Standard Operating Procedures ("hereinafter SOP's). Work instructions were used instead. A number of these were stale dated.

verification and reanalysis relative to 21CFR 117 §§ 160, 165 & 170. This deficiency was also noted in the Nestlé audit (See Exhibit 10 CAR # 23)

POSITIVE SALMONELLA

During the week of October 24, 2022, it was discovered that there was positive testing for Salmonella at the Elk Grove facility. Prerequisite and requisite programs needed to manage such microbial hazards or any other hazards were not in place to reduce or mitigate the spread of these causative agents of food borne diseases. Nor did Creative Werks during the relevant time have any Standard Operating Procedures relative to microbial hazard management or any other biological, chemical, physical or radiological hazard.

Creative Werks handles Ready To Eat foods, ("hereinafter RTE") that lack any further processing or kill step to eliminate or reduce hazards. Therefore, it is incumbent that a science risk based analysis be implemented to manage identifiable and foreseeable risks to prevent food from being adulterated and introduced into the stream of commerce for human consumption (21 CFR 117).

It can easily be inferred that the consumer complaint filed in October of 2022 was a direct result of the lack of proper food safety and hazard analysis (risk management) at Creative Werks. The complaint was tied to cereal; a RTE (See Exhibit 16). More specifically, it can be reasonably inferred that the root cause of the reported October 2022 illness was due to Creative Werks willful failure to adhere to the mandate of food safety laws and regulations relative to ensuring that food is not adulterated when it enters into the stream of commerce (21 CFR 342).

CREATIVE WERKS PURPORTED TO HAVE A SEE SOMETHING SAY SOMETHING POLICY.

I drafted a very high-level risk analysis on October 20, 2022.

On the morning of October 21, 2022, I emailed Ms. Gretchen LeMay, VP of People and asked to speak with her on Friday October 21, 2022. We agreed to meet on that following Monday (See Exhibit 17). My intent was to speak with her about the outstanding issues described above.

On Friday afternoon, I spoke with Mr. Schroeder, the owner of the company regarding outstanding compliance issues and presented him with the risk analysis dated October 20, 2022 (See attached Exhibit 18).

During our conversation, Mr. Schroeder remarked that he did not understand what I was saying to be true because Erich told him that he worked at Kraft. I told him I could not speak to Mr.

Zicher's actions, but that I was sure of what I was saying. I also told him that I had been formally trained and had years of experience with this kind of work. Mr. Schroeder also told me that I should have been trying to make nice with my boss since I had been there less than thirty (30) days.

It was my understanding that Mr. Schroeder would read the report and revert back to me for further discussion

Monday October 24, 2022 came and went and no one spoke with me nor did I have a meeting with Ms. LeMay.

On October 26, 2022, as I was leaving to go home, I was stopped, by Wendy from HR, and instructed to go into the conference room. It was at that time that Gretchen LeMay, VP of People, told me and presented me with a letter that I was being suspended for the conversation that I had with Mr. Schroeder (See Exhibit 19).

I was further told and it was memorialized in the same letter that an outside attorney would be conducting an investigation into the matters and allegations raised to Mr. Schroeder.

When I pressed Ms. LeMay on what grounds that I was being suspended on, she stated that my allegations were unfounded.

I offered her support of my position. I was instructed by her to save it for the attorney.

At no time after the conversation with Mr. Schroeder did he or anyone else follow up with me regarding the report. Nor was I involved in any type of investigation prior to being informed of my suspension.

I believe that my suspension on October 26, 2022 was in retaliation for my having presented the risk analysis to Mr. Schroeder. I also believe that I engaged in protected activity when I provided the risk analysis that detailed violations of the Food Safety Modernization and Bioterrorism Acts.

In further retaliation, I was not paid my sign on bonus on October 27, 2022 as referenced in my offer letter (See Exhibit 1).

After I requested to have an attorney present at the meeting with Creative Werks outside legal counsel, I was further retaliated against when my suspension transitioned from with pay to without pay (See Exhibit 20). Additionally, I was told by Ms. LeMay that I did not need an

attorney because this was an in-house matter and the counsel would be acting in the capacity of an independent fact finder.

I communicated to Creative Werks the adverse employment actions, which were taken against me, including but not limited to being retaliated against for identifying and raising non-compliance issues to Mr. Schroeder related to violations of FSMA. I further addressed the issue of not being afforded an opportunity to be a part of any investigation (Exhibit 21).

I requested my personnel file and it was provided. There was nothing in the file adverse except the suspension letter. I further reject the contention that I was not meeting Respondent's expectations and that they would have taken the same actions toward me. This is in direct contradiction to the fact that I was issued a written letter of suspension outlining the fact that my suspension was due to the conversation I had with Mr. Schroeder on Friday October 21, 2022 regarding the report dated October 20, 202 (See Exhibit 19).

Further, to date Creative Werks has not and cannot point to any non-retaliatory reason for suspending me. Nor can Creative Werks point to any company or public policy that I violated relative to my employment to warrant my suspension and de facto discharge/termination.

I attended a meeting with the outside counsel on December 20, 2022. Attorney Kim Ross of the Law Firm of Ford Harrison indicated that she was an independent fact finder. Attorney Ross is an employment lawyer, who did not demonstrate that she had an understanding of the subject matter contained in the risk analysis. We spoke for over 6 hours. Only an hour was spent talking about random excerpts of the report.

In January of 2023, Creative Werks counsel contacted my legal counsel and made an offer of $50,000 indicating that I could not come back to work at Creative Werks because Eric Zicher could not work with me. He also indicated that my assertions and allegations were unfounded.

I requested my personnel file again to review the findings of the investigation that supported their contentions that my assertions were unfounded. Creative Werks declined to provide me my personnel file in contravention to the Illinois Personnel Review Act or the results of the investigation (See Exhibit 22).

Craig Thorstenson also of Ford Harrison stated that Creative Werks was claiming privilege and would not be sharing the findings based on client-attorney relationship. This explanation for denying me access to their findings contained in my personnel file belies the assertion that the outside counsel from Ford Harrison was acting as an independent fact finder.

Through my legal counsel, Creative Werks was provided with my various theories of causes of actions, including but not limited to what I contend was retaliation amongst other things. I also contend that Creative Werks conspired to violate my protected rights. Creative Werks acknowledged that Creative Werks was aware of these theories and admonished me to make a counter offer, as they would not raise their offer until such time (See Exhibit 23).

I made a counter offer and their deadline to reply was April 17, 2023. Communications ceased and I filed my claim with OSHA on April 21, 2023.

RESPONDENT'S POSITION STATEMENT IN RESPONSE TO THE APRIL 21, 2023 WHISTLEBLOWER CLAIM

I reject Creative Werks position on the matter at hand. First and foremost, Creative Werks is unable to support any of its assertions with relevant facts, rules, regulations or statutes to support their contentions.

Creative Werks has tried to convolute and malign the issue with facts that are not relevant and that are taken out of context relative to the fee waiver matter. To be extremely clear, I still contend that on that day and time when I applied I did not have the funding. Further, court records will show that I demonstrated this fact.

I further reject Mr. Zicher's assertion that I was hired to write the food safety plans. Further, the mere assertion that I was hired to write the plans underscores the fact that there were not any such plans. Further, Mr. Zicher does not point to anything to support this contention.

Additionally, the construct of a food safety plan is a cross functional and multidisciplinary function. Consequently, this contention could not be legitimate. Further, Creative Werks lacked the basic infrastructure, like standard operating procedures among other things, which Mr. Zicher alleged to be responsible for[12] to even begin developing such plans.

Hence the declaratory statement from Mr. Zicher is in contradiction to Creative Werks expert witness who claims that Creative Werks was compliant. Further, by Creative Werks own admission they lacked the requisite components of a food safety plan (See Nestlé audit CAR# 1 & 2)

These two (2) competing interests and schools of thought create an unexplainable anomaly squarely putting Creative Werks in a conundrum.

[12] See FDA REPORT 3010131930 dated July 14-15, 2022 pg. 6.

I further reject the contentions of Creative Werks' expert witness who claims to be a Food Scientist, but yet in reality by her own admission on her LinkedIn page is only a microbiologist[13]. This claim of being a food scientist is disingenuous and patently false (See Exhibit 24).

Further, Dr. Knutson only has worked thirty-eight (38) months as a microbiologist in entry level positions in an industrial setting only performing routine tests, despite having a PhD according to her LinkedIn profile. Moreover, this work experience predates the enactment of any food safety law by almost ten (10) years. The concentration of Dr. Knutson's working career over the past two (2) decades seems to be centered around teaching and cannabis[14].

Further, if one is an expert, in any particular field of discipline, it would be par for the course, for the expert to be extremely familiar with governing rules, regulations, laws and best practices governing the subject matter and the rules of evidence to present such information. In addition to being able to apply them accurately and correctly as opposed to ignoring them or being in contravention of the very standards in which they allegedly contend to be proficient.

The FDA provides a rudimentary and basic understanding of the requirements and the statute outlined on the FDA's frequently asked questions webpage that is presented in non-technical and scientific terms that is available to everyone. Frequently Asked Questions on FSMA | FDA Further, by chance it happens to speak directly in detail about some of the issues that are in contention here.

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[13] According to the Bureau of Labor and Statistics: Food scientists and technologists use chemistry, biology, and other sciences to study the basic elements of food. They analyze the nutritional content of food, discover new food sources, and research ways to make processed foods safe and healthy. Food technologists generally work in product development, applying findings from food science research to develop new or better ways of selecting, preserving, processing, packaging, and distributing food. Some food scientists use problem-solving techniques from nanotechnology—the science of manipulating matter on an atomic scale—to develop sensors that can detect contaminants in food. Other food scientists enforce government regulations, inspecting food-processing areas to ensure that they are sanitary and meet waste management standards.

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Agricultural and Food Scientists, at Agricultural and Food Scientists : Occupational Outlook Handbook (visited August 3, 2023).

The Bureau of Labor and Statistics defines a Microbiologists as a person who "study microorganisms such as bacteria, viruses, algae, fungi, and some types of parasites. They try to understand how these organisms live, grow, and interact with their environments."
Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Microbiologists, at https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm (visited July 26, 2023).

[14] Schedule I controlled substance under federal law on par with LSD and heroin that is not federally regulated for human consumption.

For example, it clearly states that each facility needs a food safety plan and that each item requires a plan. Further, it is telling that Dr. Knutson did not take these and other factors into account in her analysis and that she could arrive at the conclusion she did predicated on the facts in this case.

Further, what is even more telling is that as a PhD recipient, scientist and alleged technical writer that Dr. Knutson either did not know or miserably failed to cite references in support of her theories or conclusions. This is a basic undergraduate scientific principle and even further a basic writing principle learned in grammar school.

Other telling indictments of Dr. Knutson's lack of understanding about food safety, HACCP and the precursor to HARPC and other matrices surround statements that she makes relative to the fact that there are no International Standards. One of the very things that she purports to be certified in is HACCP which takes direction from the Codex Alimentarius[15]an international standard. It is further common knowledge that FDA routinely adopts in full or in part food safety standards from the Codex Alimentarius (See Exhibit 25). Therefore, to espouse such patently false information is an indictment of sheer incompetence and unreliability. Dr. Knutson's actions are further reprehensible and unconscionable due to the fact that we live in an age where information is readily accessible and plentiful by just doing a simple Google search.

I further reject the authenticity of the alleged documents that Dr. Knutson reviewed because they were not attached as required for reference. Further, Creative Werks provided an incorrect job description that is not commensurate with the position in which I held.

I contend that Creative Werks conduct of providing an incorrect job description was deliberate, intentional and done in bad faith to support their erroneous contention that I was responsible for writing the Food Safety Plans "hereinafter FSP."

This conduct and practice of providing incorrect information is extremely telling and further supports other allegations of Creative Werks misconduct relative to providing non-relevant documents in an effort to skirt and avoid compliance with FSMA and the Bioterrorism Act of 2002. Additionally, I contend that this is an example of Creative Werks deliberate and willful actions to continue to retaliate against me and substantiate the adverse employment actions taken

[15] The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade. The United States has been a member of the Codex Alimentarius since 1963 (Members | CODEXALIMENTARIUS FAO-WHO) (International & Interagency Coordination | FDA).

against me. Additionally, it further underscores Creative Werks pattern and practice of contrivances in this and other instances.

UNSUPPORTED STATEMENTS

Dr. Knutson chose not to support her findings by fact, law, science, peer review or even a blog. Based upon that choice, this expert opinion devolves down into a mere unsupported weak opinion based on inconclusive and conclusory statements.

I further reject Dr. Knutson's contentions that Creative Werks is/was compliant with the prevailing mandates based upon the twenty-six (26) documents reviewed by Dr. Knutson. Further, in sum, Creative Werks had in excess of twenty-six (26) customers who ran multiple food items that were wrapped, naked or blended. Creative Werks' three separate (3) facilities, purchased and resold commodities for human consumption, as well as manufactured contact and non-contact food grade packaging.

Additionally, it was well documented that Creative Werks did not have preventive controls in place, as PCHF rule had not been complied with. A requisite of compliance to an adequate food safety plan and the determinative factor of preventive controls. This was affirmed and evidenced by their own admissions. (See Nestlé audit pg.1) Conclusively, these facts do not demonstrate compliance or support her opinion.

Further, as an alleged consummate expert in food safety, Dr. Knutson should have known immediately that the absence of such documents like hazard analysis, preventive controls, supply chain program, vulnerability assessment etc… does not comport with compliance. Dr. Knutson should have further known as a microbiologist that "RTE" foods that are handled and stored require an analysis to determine any associated hazards and then how to manage the risk (preventive controls). A failure to do so is a dereliction of the duty of care imposed upon Creative Werks to ensure food that is introduced into the stream of commerce is safe for human consumption and not adulterated in accordance with 21 CR 342.

Even if Dr. Knutson did not know anything else this concept would or should have definitely been in her wheelhouse as a degreed PhD Microbiologist. Sadly, this is a fundamental concept that is taught on an undergraduate level. Dr. Knutson's inability to reconcile this principle with her education and her boasting of having taught an approved curriculum over forty (40+) plus times is testament to her sheer incompetence in food safety even from a scientific perspective.

I further reject the contention that I lacked professionalism relative to speaking with the owner.

First and foremost, the company and its owner touted a mantra of a "see something say something[16]" policy that they continuously reiterated in meetings and by post.

Further, the owner on an ongoing and regular basis spoke with his employees daily about a myriad of things. He himself espoused transparency among other things and had personally on several occasions stated that he hoped that I was helping the company along.

It was with great trepidation that I approached Mr. Schroeder even after having contemplated a backlash as a response, as evidenced by my request to speak to Ms. LeMay. However, I could not reconcile in my mind how someone who builds a successful business, purports to care about their employees, tries to create a decent and palpable work environment, engages in philanthropic efforts and makes himself available and accessible to his employees would want to find themselves blindsided, hoodwinked and bamboozled about their operation. Notwithstanding being flogged with possible criminal charges and economic woes.

Further, as Dr. Knutson noted, I am held to a higher standard and I learned relatively quickly that the standards were not being met. Additionally, being held to a higher standard and being a leader means that you have to be accountable for your actions and inactions. Conversely, if something adverse had occurred without a doubt the scenario would have been "you should have known better and you should have said something."

Additionally, there are a number of instances within the industry that have occurred as a result of people not following the standards. e.g. Blue Bell creameries and Peanut Corporation of America are prime examples of companies not following basic safety rules. In particular, it was noted in a Press Release from the Department of Justice in July of 2020 that the Blue Bell Creameries Listeria case "was particularly concerning because of the disregard of basic food safety rules and the impact those actions can have on the health and safety…" according to Robert E. Craig Jr., Special Agent in Charge of the Defense Criminal Investigative Service Mid-Atlantic Field Office.

The Press Release also went on to say:

"The health of American consumers and the safety of our food are too important to be thwarted by the criminal acts of any individual or company," said Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, FDA. "Americans expect and deserve the highest standards of food safety and integrity and we will continue to pursue and bring to justice those who put the public health at risk by distributing contaminated foods in the U.S. marketplace."

[16] The FDA inspector makes note of this policy and references it in her report See Exhibit 2 pg. 16.

https://www.justice.gov/opa/pr/blue-bell-creameries-agrees-plead-guilty-and-pay-1935-million-ice-cream-listeria

Another press release from the Department of Justice, relating to a supply chain recipient of the tainted peanut butter from the Peanut Corporation of America, predating the Food Safety and Modernization Act of 2011 underscores the long time initiative and commitment of the FDA to food safety.

"Product safety has to be a high priority for every manufacturer of foods sold in the United States" says Stephen M. Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the FDA. "FDA is working with food producers to promote compliance with food safety requirements, but if problems occur and are willfully ignored, we will use all available resources to protect American consumers from unsafe food."

https://www.justice.gov/opa/pr/conagra-subsidiary-sentenced-connection-outbreak-salmonella-poisoning-related-peanut-butter

Further, as a consumer, I am concerned about the health and welfare of myself, my family and society at large, as the products that are handled at Creative Werks are common brand name, brand leading, household foods that people of all ages consume. Further, these products are not typically flagged to be high-risk consumption foods to alert vulnerable populations such as infants, children, pregnant women, the elderly or immunocompromised persons that can be adversely affected by the causative agents of food borne illness or disease.

THE LACK OF ISSUANCE OF A FDA FORM 483 DOES NOT OBVIATE THAT INFRACTIONS AND OR VIOLATIONS OF THE FOOD DRUG AND COSMETIC ACT OCCURRED AND WERE OBSERVED BY THE FDA

It is well established and documented that the FDA inspector observed, noted and made five (5) observational findings in contravention of the FFDCA (FSMA) (See Exhibit 2).

Mr. Zicher touts the fact that a 483 was not issued, but does not exhibit the presence of mind to understand the severity of the findings or he intentionally minimizes the occurrences. Additionally, the FDA inspector pointed out that there seemed to be a systemic problem related to the record keeping, facility maintenance (dock doors)[17] and pest control due to the fact that the same issues identified at Bartlett in October of 2022 were also noted from her July 2022 inspection of the Elk Grove facility (See Exhibit 2 pg. 9).

[17] Nestlé noted the deficiencies in the dock doors in their audit.

Again, the lack of proper prerequisite and requisite programs underscore the observations made at both Elk Grove and Bartlett Creative Werks facilities, as well as the Nestlé audit findings.

MR. ZICHER'S CLAIMS OF BEING A DEGREED BIOCHEMIST AND/OR A B.S. IN SCIENCE

Mr. Zicher claims on his LinkedIn page to have a BS in science and at other times a BS in Biochemistry (See Exhibit 26 and Exhibit 27). This conduct of purporting to have a degree that he does not have or skills that he cannot evidence is egregious and unconscionable at best.

Further, this assertion of having a BS in Biochemistry is telling and is juxtaposed to the subpar quality of knowledge evidenced in his work product relative to even creating the HACCP plan for the Dunkaroos non-compliant food safety plan. Mr. Zicher's overall approach to drafting the non-science-risk based document does not support his claim(s) of having a B.S. in Science let alone a B.S. in Biochemistry.

It is not likely and highly improbable that a degreed science major from an accredited institution in any applied science should lack fundamental concepts of scientific principles such as following established standardized methods. Nor should they lack basic understanding of the requests made by the FDA inspector in regards to record keeping or how to apply basic high-school science concepts to science risked based initiatives.

What is even more telling of Mr. Zicher's competency is that Mr. Zicher an alleged degreed Biochemist or some other degreed science major could not, did not and has not spoken to the issues raised relative to the non-conformities himself in any manner-lay, technical, scientific or otherwise.

Specifically, Mr. Zicher in no formidable way has ever rejected my contentions, provided any documentation, law, facts, peer review or by any other means or instrument been able to contradict or refute the actual issues that I raised. Further, he was unable to demonstrate how he reached the conclusions he asserted utilizing appropriate technical and scientific terms and principles to refute, reject or contradict the issues that I raised. This lack of responsiveness in a scientific professional manner is telling.

Additionally, Mr. Zicher never provided an action plan, inclusive of a plan of action, expectations, goals or any direction on how to approach remediating the outstanding customer and regulatory issues.

Mr. Zicher's same LinkedIn page does not support that he ever worked at Kraft as alleged. Mr. Zicher is not credible nor is he a qualified person by education, training and or job experience or

a combination thereof as defined by the FDA (21 CFR 117.3) to function in the supervisory capacity of Director of Food Safety that he is operating in. (21 CFR 117.4(c))

Further, allowing someone to infiltrate the organization through a perpetration of "working at Kraft" or alleging to have a "BS in Biochemistry" is another indictment of Creative Werks inadequate food safety and defense programs and its inherent ability to comply with FSMA and the Bioterrorism Act of 2002 that require employers to vet their employees. 21 CFR 117.4 (a)

My intention was to steward closure to the compliance gaps at Creative Werks that had existed since the PCHF rule had been implemented in 2015, but was never complied with by Creative Werks[18]. Moreover, my hope was to create and build robust food safety and defense programs that attract and retain customers and to avoid negative goodwill and minimize any potential liability that may have resulted from the consumer complaint investigated by the FDA or any other complaint.

I, Mary Madison, declare under penalty of perjury that the foregoing is true and correct.

Dated: August 15, 2023 /s/ Mary Madison

[18] Creative Werks was non-compliant prior to Mr. Zicher becoming the Food Safety Director in 2020.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 12

MARY MADISON

January 23, 2023

Creative Werks
1460 Brummel Ave
Elk Grove Village, IL 60007

RE: Response to Outcomes and Findings of investigation relative to the October 20, 2022 Risk Analysis and October 21, 2022 conversation with Mr. Steve Schroeder

To whom it may concern:

This statement is in regards to the outcomes and findings of the investigation of Creative Werks regarding the conversation of October 21, 2022 and Risk Analysis dated October 20, 2022 presented to Mr. Steve Schroeder. This statement shall serve as my official response to the findings. Further, it is requested that this statement be placed in my personnel file.

It has come to my attention that the outcomes and findings, of the investigation that Creative Werks conducted, did not support the non-compliances identified and summarily referenced in the Risk Analysis dated October 20, 2022. It has further come to my attention that Creative Werks contends that it is confident in its current Food Safety Matrix and its management. Creative Werks also asserts underlyingly that I had issue with the competency of its Food Safety Director along with a concern that I might highlight customer/client deficiencies of competencies to the customers.

It has further come to my attention that despite Creative Werks hiring me for my expertise to manage the Quality Regulatory Affairs of the company it now asserts that I think I know more than everyone else at Creative Werks.

First, in my opinion, no one knows everything and it is unreasonable and lofty to have such a mindset to which I do not subscribe. However, as a degreed Chemist with more than 30 years in quality and regulatory management and procuring a Master's Degree in the very narrow subject of Food Safety Regulatory Science from Johns Hopkins would reasonably support that I would and should have knowledge that others may not have regarding Food Safety. Within the scope of my education at Johns Hopkins, I earned very high marks and was cited for various signature works on Food Safety Analysis that is currently being used in its curriculum and I am slated to graduate with honors from this institution.

Further, my studies in Business Analytics at Harvard University is another narrow scope of discipline using a multidisciplinary approach, affords me additional knowledge and perspectives to uniquely analyze situations for determinative and cutting edge outcomes. It is also my intent to finish this program with distinction.

Based upon the assertions and contentions made by Creative Werks, it reasonably leads me to believe that there are communications being made regarding my professionalism, competency, understanding and application of the current statutes, regulations and rules pertaining to the Food safety Modernization Act and the operations at Creative Werks, since raising the non-compliance issues in October of 2022. Such patently false assertions, by Creative Werks, concerning my intellectual capacity and competency are not only affront to me and my professional standing; but are defamatory and an affront to two (2) of the most prestigious, esteemed and elite learning institutions in the world.

In sum, I reject the assertions and contentions inferred and made by Creative Werks regarding the Risk Analysis, my professionalism and my competency. Specifically, the crux of the Risk Analysis reiterated undisputed facts and documented occurrences noted by a federal inspection and various second (2nd) and third (3rd) party audits. In addition, it highlighted that other clients sought almost a total of one hundred and fifty (150) compliance related materials for nearly more than two (2) years. Moreover, documentation revealed and supports that Creative Werks had been apprised of these deficiencies for a good span of time prior to the October Risk Analysis.

Additionally, the Risk Analysis was a very high overview of process and operational gaps that needed addressing by the company; especially in view of the most recent consumer complaint investigated by the FDA in September of 2022, in which I participated. The analysis was not a critique of the business nor of its management nor of its staff. It was merely a Risk Analysis. Further, the current Food Safety Director's competency is well established. This competency is demonstrated through his education as a Biochemist; his work history at Kraft Foods and other places along with his PCQI and HACCP certifications among others.

Tracing the root cause of the process and operational gaps, identified in the October 20, 2022 analysis, suggest that the noncompliance dates back to as recent as 2016. Risk Analysis is an essential function of the Food Safety and Modernization Act and the job that I was hired to perform. The analysis was not meant to be an affront to the integrity of the company's operations, but the catalyst to compliance to FSMA and other statutory requirements.

Undoubtedly, the October 20, 2022 Risk Analysis, outlining the various non-compliances, and the October 21, 2022 conversation, led to my suspension and the various other adverse employment actions taken against me. Specifically, I am baffled as to how operational issues quickly devolved into a human resource issue for which I was not afforded the courtesies of an audience with the management team or HR to engage in dialogue to address the issues raised in the Risk Analysis prior to the suspension.

Further, I am more concerned that the investigatory process was conclusory and lacked independent third (3rd) party subject matter technical expertise in Food Safety and Regulations that would have allowed for a proper and thorough evaluation of the Risk Analysis to either validate or disprove its analysis and conclusions. What is even more disconcerting is the lack of acknowledgement or deference towards compliance to the Food Safety mandates that govern and underscore public safety and health initiatives. This is an affront to society at large, to willfully and recklessly, fail to ensure that products introduced into the stream of commerce for human consumption are safe.

Moreover, I contend that the assertions and contentions made by Creative Werks are false and pretextual in regards to their alleged outcomes and findings to coerce my separation from the company. I further contend that others who have violated public policy have been treated more favorably than I have and did not suffer any adverse actions, such as suspension. Finally, I contend, the treatment I am receiving is retaliatory and based upon me engaging in protected activity, my race and my gender.

Sincerely yours,

Mary Madison

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 13

EEOC Form 5 (1/09)

EEOC REC'D 21 AUG 2023

Exhibit 1

CHARGE OF DISCRIMINATION

This form is affected by the Privacy Act of 1974. See enclosed Privacy Act Statement and other information before completing this form.

Charge Presented To: ☐ FEPA ☒ EEOC

Agency(ies) Charge No(s): 2024CR0389
440-2023-09356
240925.038

and EEOC

State or local Agency, if any

Name (indicate Mr., Ms., Mrs.)	Home Phone (Incl. Area Code)	Date of Birth
Ms. Mary Madison	7732979569	09/26/1968

Street Address: 9758 S. Charles — City, State and ZIP Code: Chicago, IL 60643

Named is the Employer, Labor Organization, Employment Agency, Apprenticeship Committee or State or Local Government Agency That I Believe Discriminated Against Me or Others. (If more than two are named, list under PARTICULARS below.)

Name	No. Employees, Members	Phone No. (Incl. Area Code)
Creative Werks, LLC	500+	6308602222

Street Address: 1460 Brummel — City, State and ZIP Code: ElkGrove Village, IL 60007

Name	No. Employees, Members	Phone No. (Incl. Area Code)

Street Address — City, State and ZIP Code

DISCRIMINATION BASED ON (Check appropriate box(es).)

☒ RACE ☐ COLOR ☒ SEX ☐ RELIGION ☐ NATIONAL ORIGIN
☒ RETALIATION ☐ AGE ☐ DISABILITY ☐ GENETIC INFORMATION
☒ OTHER (Specify) harassment

DATE(S) DISCRIMINATION TOOK PLACE: Earliest 10/26/2022 Latest 11/08/2022
☐ CONTINUING ACTION

THE PARTICULARS ARE (If additional paper is needed, attach extra sheet(s)):

I was suspended on October 26, 2022 in retaliation for raising violations of the FFDCA as amended by FSMA to the owner of the company on Friday October 21, 2022. My employer provided a letter stating the same. [redacted]
I was never a part of any investigation.
I was subject to further retaliation and harassment when I was not paid my bonus that was due and owing to me on October 27, 2022. [redacted]
I was further retaliated against and harassed when my paid suspension was converted to a suspension without pay on November 8, 2022 after telling my employer that they retaliated against me and for asking for legal counsel to attend the mandatory meeting with their outside legal counsel.
I was told by my employer that they were an independent fact finder.
Further, my employer conspired with outside counsel to further violate my protected rights to create a pretext.
I was further harassed when I had to go to their outside legal counsel under the premise of them being an independent fact finder. On December 20, 2022, I spent over 6 hours speaking with their counsel, with over 5+ hours speaking about other issues not related to the issues that I was supposed to be speaking with them about .
On January 18, 2023, the law firm indicated that my assertions were unfounded and that I could not come back to work because [redacted] could not work with me.
On January 20, 2023, the law firm claimed privilege when I asked for the investigation findings. [redacted]
The firm and my employer refused to share the investigation findings and my personnel file.
On January 23, 2023, I informed my employer that I had been treated differently than others who had violated company and public policy; including [redacted] a white male.
I am technically still on suspension.

OFFICIAL SEAL
EDWIN WALKER
Notary Public - State of Illinois
My Commission Expires 08/22/2026

I want this charge filed with both the EEOC and the State or local Agency, if any. I will advise the agencies if I change my address or phone number and I will cooperate fully with them in the processing of my charge in accordance with their procedures.

I declare under penalty of perjury that the above is true and correct.

08/17/2023
Date — Charging Party Signature

NOTARY – When necessary for State or Local Agency Requirements

I swear or affirm that I have read the above charge and that it is true to the best of my knowledge, information and belief.

SIGNATURE OF COMPLAINANT

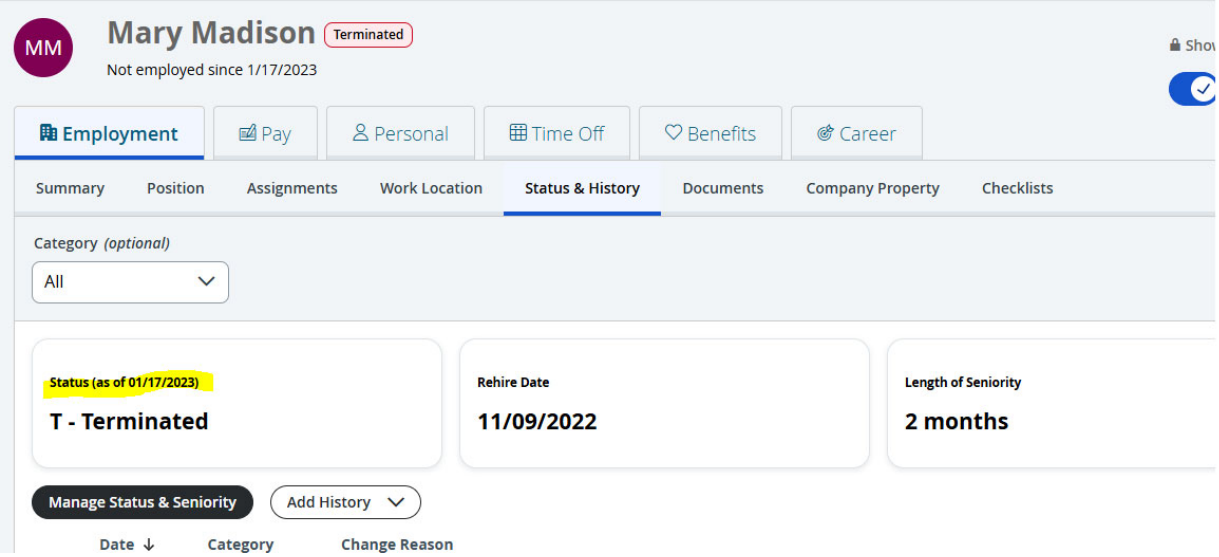
SUBSCRIBED AND SWORN TO BEFORE ME THIS DATE (month, day, year)
8/18/23

DEPT. OF HUMAN RIGHTS
INTAKE DIVISION
09/25/2023
RECEIVED
BY:_____

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 14


MM
Mary Madison
Terminated
Not employed since 1/17/2023
Employment
Pay
Personal
Time Off
Benefits
Career
Summary
Position
Assignments
Work Location
Status & History
Documents
Company Property
Checklists
Category (optional)
All
Status (as of 01/17/2023)
T - Terminated
Rehire Date
11/09/2022
Length of Seniority
2 months
Manage Status & Seniority
Add History
Date
Category
Change Reason

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 15

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

DECLARATION OF ERICH ZICHER
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

1. I, Erich Zicher, have personal knowledge of all statements set forth in this Declaration, and if called to testify, will assert same under oath and under penalty of perjury.

2. I, Erich Zicher have been employed by Creative Werks LLC ("Creative Werks") as its Director of Food Safety since November 2020 through the present.

3. In my capacity as at the Manager of Creative Werks' Director of Food Safety, my responsibilities include(d) coordination of regulatory, compliance, and quality activities relative to Creative Werks' operations, including but not limited to hiring, scheduling, workflow, investigations, safety, food defense, and safety plans, as well as, internal, external, federal, state and local compliance audits relative to the Food Drug and Cosmetic Act (FD&C) and other relevant statutes and the like.

4. Prior to working for Creative Werks, I worked for another large food packaging company since 2012, where I served as a Quality Assurance Manager, with many of the same responsibilities I have at Creative Werks. I have training and credentials with respect to Food Safety Preventative Controls, Food Defense, Implementing SQF Systems, Food Safety and Sanitation for Food Plants, Food Processing Sanitation/Hygiene and HACCP certification (Hazard Analysis and Critical Control Points)

5. At all times that Mary Madison ("Madison") was employed by Creative Werks, I was her immediate supervisor, and Ron Sammeth was my supervisor, who answered to Mr. Steve Schroeder, the President of Creative Werks.

6. Shortly after Plaintiff was hired, an FDA inspector visited the Creative Werks' newer Bartlett site on September 28-29, 2022.

7. The inspection was "pre-announced" and "routine" and included Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Control for Human Food Subparts, and Preventative Controls and Sanitary Human Food Operations.

8. Madison was present during the September 2022 FDA Inspection, and at some point over the 2 day inspection, the FDA inspector first notified Creative Werks of a 5/21/22 customer "Pepsi Cheeto" complaint. Creative Werks had no prior knowledge of this complaint. In response, Creative Werks then shared with the inspector a prior similar customer complaint that had already been remediated.

9. The two Pepsi Cheeto complaints related to discoloration of sealing packaging due to excess induction heating utilized when packing the products at issue. Based on the written complaints, no parties reported seeking any medical attention. .

10. The above noted prior remediation effort engaged in by Creative Werks with respect to the previously known "Cheeto report" was disclosed to the FDA inspector, and it was explained that Creative Werks no longer packaged the product at issue. This was reflected in the September 2022 FDA inspection report.

11. Prior to and during Plaintiff's employment with Creative Werks, Creative Werks' food safety programs and facilities were regularly audited and inspected by third parties entities, including the FDA (i.e. regulatory audits), customer audits by highly trained food safety auditors, and SQF audits. My primary job duties, related in part, participation in the

aforementioned audits, addressing the results of audits/inspections, knowledge of Creative Werks' food safety programs, food and safety related regulatory compliance, and required my company-wide understanding of its compliance with same, its operations, and actions/procedures engaged in to comply with all food regulations, audit findings, and inspections.

12. Creative Werks, has been in operation as a food packer/co-packer since 1999. Over that time, it has been the subject of hundreds of inspections and food safety audits over the years, and based upon my knowledge and review of historical records maintained, Creative Werks has never received a 483 Notice from the FDA with respect to any safety concern or otherwise, nor has it lost any business with any customer relating to same.

13. According to my understand and based upon a review of the FDA website (www.fda.gov), an FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. In my professional experience, if there was a material FDA regulatory violation or concern, a Form 483 would be issued by the FDA.

14. Prior to and during my employment with Creative Werks, there have been FDA audits (i.e. regulatory audits) conducted by the FDA and by other regulatory bodies upon the request of the FDA, with respect to Creative Werks. The purpose of these audits, in part, was to determine compliance with FDA and FSMA regulatory schemes.

15. With respect to the September 2022 FDA Inspection, the conclusion was "NAI" which means "No Action Indicated." In my experience, while this does not mean that the FDA has not found anything reportable, it means that no material or repeated deficiencies are being noted by the FDA as requiring attention, explanation or remediation.

16. After the September 2022 FDA inspection, I sent emails to other employees summarizing the written findings of the FDA. (Accurate copies of these emails are attached as Group

Exhibit 3 to the Statement of Undisputed Facts.) Madison supplemented my email to the Creative Works team. (Ex. 4 to the Statement of Undisputed Facts).

17. In 2022, the year that Madison worked for Creative Werks, there were fourteen (14) independent/third party food safety customer audits and two (2) regulatory (FDA) audits.) In my opinion (and based on the face of the audit results), none of these audits revealed any material food safety plan or regulatory non-compliance issues (i.e. in each instance passing or above passing results). In my experience, there is always room for improvement with respect to safety, which is why Creative Werks also has an active Continuous Improvement Plan. This includes, but is not limited, to addressing any audit findings suggesting or requiring improvements, alternations or changes of procedures.

18. Similarly, in 2023, there were fifteen (15) independent customer food safety/regulatory audits in addition to two (2) SQF audits. In my opinion, none of them revealed any material food safety plan or regulatory non-compliance issues nor did they facially indicate material deficiencies.

19. Creative Werks is subject to anual SQF audits as well. SQF audits, in part, is a third party audit, reflecting industry wide required food safety standards to evaluate a food facility's food safety and quality management systems to ensure they meet the requirements of SQF code and Global Food Safety Initiative standards. SQF audits are very detailed and extensive, they are relied upon by Creative Werks and Creative Werks clients to gauge, in part, Creative Werks compliance with relevant food safety standards and regulatory compliance.

20. Creative Werks had an SQF Food Safety Audit on March 29. 2022. An accurate copy of this audit is attached as Exhibit 6 to the Statement of Undisputed Facts. This SQF audit included a review of Creative Werks' four (4) food safety plans that were in effect at the time. Out of a potential score of 100, Creative Werks received a score of 96. This is "Excellent" and demonstrates a high level of compliance.

21. In 2022, Nestle conducted an audit, and Madison was tasked, in part, with addressing certain aspects of its findings. An accurate copy of the Nestle Audit (in relevant part) is attached as Exhibit 6 to the Statement of Undisputed Facts. Pursuant to Nestle's own definition in the audit, the findings were "Satisfactory," which is defined therein as "The audit results identified a few issues in need of attention, but none shows significant or fundamental weakness in controls, compliance, or operations." (Id.)

22. As was the custom, Creative Werks subsequently addressed all aspects of the Nestle audit, came up with appropriate measures, and they were signed off by Nestle as sufficient and meeting their audit requirements. Indeed, as with many customers, Creative Werks has standing meetings every two (2) weeks, to review its safety and food procedures, and to engage in continuous improvement of its practices. (See portion of Remediation Approval given by Nestle at Ex. 7 to Statement of Undisputed Facts).

23. Madison was assigned to work on a food safety plan that was based on a model published by the Food Safety Preventative Controls Alliance (FSPCA). I consider this to be a gold-standard source, in part, because it is jointly created and published by the FDA, the Institute for Food Safety, and FDA Risk Based Preventative Controls for Human Food Regulations. The food safety plan version that Madison was tasked with rolling out to improve the other food safety plans had been created by me to address the unique ingredients, risks and measures required for Creative Werks "Dunkaroos" product line. The template, upon which the Dunkaroos food safety plan was based on, was derived from a sample Food Safety Plan example in the FSPCA publication , and supplemented to provide additional details relating to the specific product at issue, including but not limited to a tailored risk analysis and customer specifications. This publication is also required reading for Preventive Controls Qualified Individual (PCQI) licenses, a license held by Madison.

24. On or about October 21, 2022, Madison tendered a document that she drafted entitled Regulatory Business Problem (hereinafter "Legal Analysis") to Mr. Steve Schroeder.

25. The Legal Analysis was shared with me for my review upon Madison's tendering of same, prior to her being suspended. I viewed and opined her Legal Analysis to be wholly deficient, unprofessional, alarmist, and error ridden.

26. I considered the Legal Analysis to be a poor work product, full of gross misstatements, reflecting a misunderstanding of applicable regulatory compliance requirements, consisting of false assertions of fact, lacking in research, unprofessional, reflecting a wholesale misunderstanding of Creative Werks' safety culture, reflecting a gross mischaracterization of events, reports at Madison's disposal and/or audit findings, and generally reflecting alarmist, non-rational, and unsubstantiated conclusions/repercussions. In my opinion, Madison's Legal Analysis reflected Madison not being qualified for the position she was hired for.

27. Madison's did not tender or attempt to tender her Legal Analysis to me prior to giving it to Creative Werks' President, Steve Schroeder.

28. Madison's Legal Analysis states, in its abstract and first substantive sentence, that Creative Werks' "non-compliance to the relevant statutes, standard and regulations under the FSMA is an inherent systematic and systematic issue through the organization that creates irreparable harms for all stakeholders." (Ex. 8) I consider(ed) this statement to be false, contrary to the entire philosophy of Creative Werks, directly contradicted by dozens of regulatory, SQF and customer audits finding otherwise, and reflecting an alarmist conclusion and is contrary to facts as I understand and/or understood them.

29. Madison's Legal Analysis also stated, in part, that "Other stakeholders could suffer injury, illness, or death, in addition, other can suffer loss of employment and economic stability." (Ex 8). This statement is and was considered false by Creative Werks, did not appear to be based on any rational analysis, ignored the safety plans and regulatory compliance engaged in by Creative Werks, and was both wholly unsubstantiated and asserted alarmist conclusions.

30. The Legal Analysis, asserts that Creative Werks had "culpability" due to its "breach of contract." (Ex. 8). Creative Werks was not aware of and denies it had culpability with respect to any breaches of contract as asserted by Madison. To the extent Madison predicates this assertion based on a 2022 audit conducted by Nestle, this conclusion is wholly inconsistent with said audit findings, which were "Satisfactory" as deemed by said client.

31. I also have personal knowledge of the follow up actions engaged in by Creative Werks with respect to the 2022 Nestle audit that Madison worked on. As in the past with such audit results, any areas for improvement or otherwise required by this customer, were the subject of a remediation plan (and actions to effectuate same), which were signed off and approved by the client to meet their needs and/or Creative Werks. An example of the approved remediation efforts, approved of by Nestle are reflected in Exhibit 7 to the Statement of Undisputed Facts.

32. The Legal Analysis asserts that Creative Werks was in breach of its "fiduciary duties." Creative Werks disagreed that there was any breach of contract with Nestle and disagreed with Madison's legal conclusions.

33. Madison's Legal Analysis asserted that "since its inception of the Preventative Controls regulations, Creative Werks has never been compliance and has had repeated violations from numerous customer audits. (Ex. 8). Creative Werks deeply disagrees and disagreed with this gross mis-statement which is belied by my personal knowledge as well as dozens of audits and inspections finding the opposing to be true.

34. The Legal Analysis, stated in part, that "It can be reasonably inferred there is a high probability factor that our non-compliance is a root cause in lost business opportunities such as Pepsi." (Ex. 8). This statement was of great concern to Creative Werks because, to our knowledge, there were never any non-compliance issues that ever resulted in the lost business with Pepsi or any other client for that matter. Madison's conclusion in this respect, was clearly not researched, and reflects the making of material and sweeping conclusions

and recommendations based on her poor work product and/or intentionally misrepresenting issues relating to Pepsi.

35. The Legal Analysis, stated in part, that non-compliance with regulations would subject Creative Werks to "an increase in lost revenue…". This statement was of significant concern to Creative Werks. To my knowledge, Creative Werks has not lost revenues in the past due to any regulatory non-compliance.

36. The Pepsi Cheeto product packaging project was terminated solely due to excessively high processing costs due to manual labor involved, and would have required capital cost improvements to correct, that were deemed excessive.

37. Madison's Legal Analysis stated that "Noncompliance negatively affects our sustainability, goodwill, and profitability here at Creative." (Ex. 8). Creative Werks understood this to be a false statement and false premise, entirely contradicting the compliance initiatives and evidence of regulatory compliance that had been internally and externally confirmed, by the FDA, customer audits, SQF audits and my own knowledge. I am further not aware of any non-compliance with regulatory schemes impacting Creative Werks sustainability, goodwill or profitability.

38. Madison's Legal Analysis, stated in part, that there was an expiration of civil liability as of October 2023, as it related to the Pepsi Cheeto product. (Ex. 8). Given that there had never been a confirmed injury nor reason to expect any injuries, raising this issue reflects faulty reasoning and irrational conjecture by Madison. This is another example of Madison's failure of clear thinking, a lack of understanding of understanding of basic risk assessment, a lack of research, distortion of fact (or assumptions) and alarmist concerns.

39. Madison's statement regarding "civil liability" relating to the Pepsi Cheeto was disconcerting, in part, because there was/is no evidence of any individual requiring or obtaining medical attention due to any Pepsi Cheeto product and/or that any discoloration on packaging several years ago would or could harm any consumer.

40. Madison's Legal Analysis raised the issue topic of potential criminal liability based on her understanding of the discoloration issue raised in the FDA Cheetos consumer complaint, even though: (a) remediated by Creative Werks nearly two (2) years earlier, with no injuries, (b) an FDA acknowledgement of the remediation measures taken by Creative Werks. (see Ex. 2); (c) and generally reflecting a lack of logical reasoning and/or understanding as to the nature of food safety violations that would implicate any criminal liability.

41. Madison asserts in the Legal Analysis that Creative Works also lacked change control management, to remain compliant with FSMA and other relevant statutes. (Ex. 8). Creative Werks strongly disagreed with this conclusion. To the extent Madison bases this upon the results of the 2022 Nestle audit that she had access to, Creative Werks believe(s)/believed her conclusions to be overly-broad, misleading and in-accurate.

42. I am not aware of, nor have I ever reported to Mr. Schroeder or the Company of:

a) allegations that Creative Werks may have potential criminal liabilities with respect to any of its operations, actions, in-actions or compliance with any regulatory scheme;

b) any assertions of Creative Werks having any systematic failure to comply with FSMA or other regulatory schemes; .

c) allegations of any breaches or potential breaches of fiduciary duties;

d) falsification of documents by Creative Werks to any regulatory body;

e) words to the effect that Creative Werks had been improperly interpreting, analyzing, and applying relevant food safety statutes;

f) words to the effect that Creative Werks encouraged a disregard for the law;

g) words to the effect that Creative Werks has ever (or year over year) been consistently been out of regulatory compliance with the FD&C Act;

h) words to the effect that Creative Werks improperly interprets, or improperly analyses, and/or misapplies relevant food safety statutes;

i) words to the effect that Creative Werks has a culture opposed to the transparency mantra of Creative Werks; and/or

j) words to the effect that Creative Werks encourages a disregard for the law.

43. Creative Werks employed approximately forty-two (42) workers, with an entire department consisting of employees who oversee its food safety regulatory compliance.

44. Creative Werks further deploys structured programs and training that develop employees' technical skills, increase awareness, manage risk, and drive increasing levels of excellence within the quality department's operation, all in keeping with or exceeding industry norms.

45. Creative Werks participates in programs, including some in conjunction with its clients, for continuing improvement programs often leading to bi-weekly third party meetings and client agreements on any required remediations.

46. Creative Werks has extremely sophisticated customers (some of whom are the largest confectionaries and food manufacturers in the World), who rely on Creative Werks to meet all food safety regulations, but who also require third party verifications (such as SQF audits), in addition to client audits and access to FDA audit inspection results.

47. An SQF audit was conducted in 2023, and none of the issues raised by Madison in her Legal Analysis were reflected, confirmed or indicated in said audit.

I declare under penalties of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) that the foregoing is true and correct.

Signed by: Executed on June 9, 2025

Erich Zicher

A2ABBA3A5C8D424...

_____ (Signature)

Erich Zicher

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 16

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

DECLARATION OF STEVE SCHROEDER

1. I, Steve Schroeder, have personal knowledge of all statements set forth in this Declaration, and if called to testify, will assert same under oath and under penalty of perjury.

2. I am the founder of Creative Werks LLC ("Creative Werks"), which started business in 1999, as a food packer/co-packer.

3. Since my founding of Creative Werks, I have served as its President, and have been involved in all aspects of its management and operations, which includes direct involvement in its safety and regulatory compliance with all applicable regulatory schemes, applicable to food packers/co-packers. In this capacity too, I have had dedicated directors, managers and employees in charge of food safety and compliance with relevant standards and regulatory schemes, who regularly report to me and provide me with all relevant information regarding same. Creative Werks prides itself on the food safety culture it has built and maintained over a period of 25 years.

4. During Mary Madison's ("Madison") employment, Ronald Sammeth was the Chief Operating Officer, who was a supervisor to Mr. Eric Zicher, the Director of Food Safety.

5. Prior to and during Plaintiff's employment with Creative Werks, Creative Werks' food safety programs and facilities were regularly audited and inspected by third party entities, including the FDA (i.e. regulatory audits), customer audits (some by Fortune 100 companies) by highly trained food safety auditors and SQF audits. The SQF audits are intense, 3 days audits that occur every year. In my capacity as President, I have been made aware of and received regular reports on the aforementioned audits, addressing the results of audits/inspections, As part of this process, I have personally met with many of these auditors as part of their inspections. I have significant knowledge of Creative Werks' food safety programs and its food and safety related regulatory compliance, and I have

knowledge of its compliance with same, its operations, and actions/procedures engaged in to comply with all food regulations, audit findings, and inspections.

6. Since 1999, Creative Werks has been the subject of many dozens of inspections and food safety audits over the years, and based upon my knowledge and review of historical records maintained, Creative Werks has never received a 483 Notice from the FDA with respect to any safety concern or otherwise, nor has it lost any business with any customer relating to same.

7. According to my understanding and based on my 25 years of owning and operating a food packing company, an FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute material violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

8. I was made privy with respect to the result of a September 2022 FDA inspection through emails from Mary Madison and Zicher. Both reported nominal findings in their email reports.

9. On or about October 21, 2022, Madison tendered a document to me entitled "Regulatory Business Problem" (hereinafter "Legal Analysis") which she indicated she authored. She also made an oral presentation to me and made statements outside of the scope of the Legal Analysis content.

10. I considered the Legal Analysis to be a poor work product, full of gross misstatements, reflecting a misunderstanding of applicable regulatory compliance requirements, consisting of false assertions of fact, lacking in research, unprofessional, reflecting a wholesale misunderstanding of Creative Werks' safety culture, reflecting a gross mischaracterization of events, reports at Madison's disposal and/or audit findings, and generally reflecting alarmist, non-rational, and containing several unsubstantiated conclusions. I considered her report to non-sensical. In my opinion, Madison's Legal Analysis reflected Madison not being qualified for the position she was hired for. Her reports and my Comments regarding same were immediately forwarded to our HR department and others for review and comment.

11. Madison told me that she did not tender her Legal Analysis to her supervisor or to the COO prior to giving it to me.

12. Madison's Legal Analysis states, in its abstract and first substantive sentence, that Creative Werks' "non-compliance to the relevant statutes, standard and regulations under the FSMA is an inherent systematic and systematic issue through the organization that creates irreparable harms for all stakeholders." (Ex. 8) I consider(ed) this statement to be false, contrary to the entire philosophy of Creative Werks, directly contradicted by many dozens, if not more than 100, regulatory, SQF and customer audits finding otherwise, and reflecting an alarmist conclusion and is contrary to facts as I understand and/or understood them.

13. Madison's Legal Analysis also stated, in part, that "Other stakeholders could suffer injury, illness, or death, in addition, others can suffer loss of employment and economic stability." (Ex 8). This statement is and was considered false by Creative Werks, did not appear to be based on any rational analysis, ignored the safety plans and regulatory compliance engaged in by Creative Werks, and was both wholly unsubstantiated and asserted alarmist conclusions.

14. The Legal Analysis, asserts that Creative Werks had "culpability" due to its "breach of contract." (Ex. 8). Creative Werks was not aware of and denies it had culpability with respect to any breaches of contract as asserted by Madison. To the extent Madison predicates this assertion based on a 2022 audit conducted by Nestle, this conclusion is wholly inconsistent with said audit findings, which were "Satisfactory" as deemed by said client. Moreover, because Nestle did the audit themselves, they are inherently aware of its results and it has never alleged any type of breach with respect to same and Nestle continues to be a client of Creative Werks.

15. The Legal Analysis asserts that Creative Werks was in breach of its "fiduciary duties." Creative Werks disagreed that there was any breach of contract with Nestle and disagreed with Madison's legal conclusions.

16. Madison's Legal Analysis asserted that "since its inception of the Preventative Controls regulations, Creative Werks has never been compliance and has had repeated violations from numerous customer audits. (Ex. 8). Creative Werks deeply disagrees and disagreed with this gross mis-statement which is belied by my personal knowledge as well as hundreds of audits and inspections finding the opposing to be true. Madison, moreover, had only been with the Company for a few weeks when drafting said Legal Analysis.

17. The Legal Analysis, stated in part, that "It can be reasonably inferred there is a high probability factor that our non-compliance is a root cause in lost business opportunities such as Pepsi." (Ex. 8). This statement was of great concern to Creative Werks because, there were never any non-compliance issues that ever resulted in the lost business with Pepsi or any other client for that matter. Madison's conclusion in this respect, was clearly not researched, and reflects the making of material and sweeping conclusions and recommendations based on her poor work product and/or intentionally misrepresenting issues relating to Pepsi.

18. The Legal Analysis, stated in part, that non-compliance with regulations would subject Creative Werks to "an increase in lost revenue…". This statement was of significant concern to Creative Werks with respect to Madison. To my knowledge, Creative Werks has not lost revenues in the past due to any regulatory non-compliance, nor did Madison cite to any instances of same.

19. The Pepsi Cheeto product packaging project was terminated solely due to excessively high processing costs due manual labor involved, and would have required capital cost improvements to correct, that were deemed excessive. There was no link between any complaint and the cessation of that product packaging. For Madison to have asserted

otherwise, reflected a critical lack of research regarding a material assertion in her Legal Analysis and she generalized her misunderstanding to reach more far-reaching incorrect conclusions about Creative Werks' risks.

20. Madison's Legal Analysis stated that "Noncompliance negatively affects our sustainability, goodwill, and profitability here at Creative." (Ex. 8). Creative Werks understood this to be a false statement and false premise, entirely contradicting the compliance initiatives and evidence of regulatory compliance that had been internally and externally confirmed, by the FDA, customer audits, SQF audits and my own knowledge. I am further not aware of any non-compliance with regulatory schemes impacting Creative Werks' sustainability, goodwill or profitability. Madison did not cite any actual instance of her concerns.

21. Madison's Legal Analysis, stated in part, that there was an expiration of civil liability as of October 2023, as it related to the Pepsi Cheeto product. (Ex. 8). Given that there had never been a confirmed injury nor reason to expect any injuries, raising this issue reflects faulty reasoning and irrational conjecture by Madison. This is another example of Madison's failure of clear thinking, a lack of understanding of basic risk assessment, a lack of research, distortion of fact (or assumptions) and alarmist concerns/conclusions.

22. Madison's statement regarding "civil liability" relating to the Pepsi Cheeto product was disconcerting, in part, because there was/is no evidence of any individual requiring or obtaining medical attention due to any Pepsi Cheeto product and/or that any discoloration on packaging several years ago would or could harm any consumer and/or any evidence of negligence, wrongdoing or malfeasance on the part of Creative Werks, nor did Madison cite any evidence of same.

23. Madison's Legal Analysis raised the issue topic of potential criminal liability based on her understanding of the discoloration issue raised in the FDA Cheetos consumer complaint, even though: (a) remediated by Creative Werks nearly two (2) years earlier, with no injuries, (b) an FDA acknowledgement of the remediation measures taken by Creative Werks. (see Ex. 2); (c) and generally reflecting a lack of logical reasoning and/or understanding as to the nature of food safety violations that would implicate any criminal liability.

24. Madison asserts in the Legal Analysis that Creative Works also lacked change control management, to remain compliant with FSMA and other relevant statutes. (Ex. _). Creative Werks strongly disagreed with this conclusion. To the extent Madison bases this upon the results of the 2022 Nestle audit that she had access to, Creative Werks passed this audit and believe(s)/believed Madison's conclusions to the contrary to be materially misleading and in-accurate.

25. When presenting her Legal Analysis, Madison made many oral statements to me, some of which I incorporated into a contemporaneous email that I sent to Gretchen Lemay, an accurate copy of which is attached as Exhibit 9 to the Statement of Undisputed Fact. Madison made a blanket statement to me that Creative Werks does not follow food safety

guidelines. In response, when I noted that the Company is subject to many audits by clients, regulators and third party auditors finding otherwise, Madison stated that they (the auditors) "do not necessarily know what they are doing". This reflected to me deflection of her poor work product and a gross misunderstanding of industry standard checks and balances, a lack of trust over regulatory bodies conducting audits, and her non-rational expressions that other persons engaged in her field, co-employees and customer auditors were not qualified to do their jobs.

26. Madison admitted to me that she did not share her Legal Analysis with her supervisors before bringing it to my attention. While Creative Werks generally has a transparency culture, given the magnitude and nature of the Legal Analysis and her oral statements, I found this to be a significant breach of corporate protocol and common sense for her not to have run it by any supervisor before bringing it to my attention. Also, given her short tenure at the Company, I found it shocking for her to present firm-wide allegations of mis-perceived risk issues without having had the experience, first-hand knowledge and/or research to back up her claims

27. Madison further stated to me that Creative Werks should not rely upon representations and/or testing done by Creative Werks' clients with respect to food products provided by them. In my opinion, this reflected a wholesale misunderstanding of the applicable regulations that allows Creative Werks to rely on same.

28. Madison stated that when she participated in a September 2022 FDA inspection, that her supervisor, Erich Zicher, "provided too much information" to the FDA. I found this to be troubling, as Madison was both asserting that the Company was not being transparent enough and that it was also being too transparent. Also, she provided no citation to any particular information that was provided to the FDA but should not have been.

29. Madison also expressed concern over the September 2022 FDA inspection, grossly exaggerating and misstating the results of that audit. When I pointed out that the FDA did not issue a 483 Notice, Madison dismissed that entirely and merely stated, "I did not know what the FDA person was writing down." This by itself, reflected that she had an unstated agenda, and reflected a basic lack of FDA inspection protocols, because the FDA provided detailed findings to Creative Werks in its audit report, as they do with all of their inspections, and if there were a material finding or concern, it would not be hidden by the FDA inspector. This demonstrated to me additional deflection of poor work product by Madison.

30. When delivering her Legal Analysis, Madison also raised an issue about an x-ray machine being used on one of the food packing lines. She asserted that even though it was deemed GRAS (Generally Recognized as Safe), she incorrectly indicated Creative Werks cannot use that designation. She did not cite why this was the case. Moreover, Madison stated that additional measures should be taken to ensure no radiation leaks even though Creative Werks already utilized the manufacturer's recommended maintenance schedule. When questioned at that time, Madison admitted that she did not look up the recommended

maintenance of the x-ray machine in question before meeting with me and she told me she had not inspected the x-ray machine herself

31. I was involved in the decision to initially suspend and later terminate Madison based on Creative Werks' determination that Madison was not fit for the job she was hired for, evidenced by the materially flawed content of her Legal Analysis, similarly unprofessional oral statements to me and the method she used to bring these to the Company's attention.

32. Unlike Madison, Zicher has never demonstrated a lack of professionalism nor evidenced that he was not fit for the job he was hired for, in any respect. I have never found material faults in his methods and/or work results.

33. Unlike Madison, Zicher has never reported to me or the Company any:

a) allegations that Creative Werks may have potential criminal liabilities with respect to any of its operations, actions, in-actions or compliance with any regulatory scheme;

b) any assertions of Creative Werks having any systematic failure of Creative to comply with FSMA or other regulatory schemes or cognitive recognition of same;

c) allegations of any breaches or potential breaches of fiduciary duties;

d) assertions of falsification of documents to Creative Werks, customer or regulatory body;

e) words to the effect that Creative Werks had been improperly interpreting, analyzing, and applying relevant food safety statutes;

f) words to the effect that Creative Werks encouraged a disregard for the law;

g) words to the effect that Creative Werks has ever (or year over year) has been consistently been out of regulatory compliance with the FD&C Act;

h) words to the effect that Creative Werks improperly interprets, or improperly analyses, and/or misapplies relevant food safety statutes;

i) words to the effect that Creative Werks has a culture opposed to the transparency mantra of Creative Werks; and/or

j) words to the effect that Creative Werks encourages a disregard for the law.

34. More broadly, at no time has Zicher engaged in any actions giving rise to the need to be the subject of any disciplinary action, nor has he turned in work product (written or oral) that:

a) I considered to be unprofessional, unfounded, and/or un-researched;

b) reflected a gross misunderstanding of the Company's operations;

c) reflected gross misstatements about the Company's culture,

d) that was materially irrational and/or alarmist;

e) reflected a lack of professionalism;

f) made material suggestions to operational changes outside of his area of expertise;

g) reflected a lack of understanding of the role, import and reliance on third party audits;

h) suggested that FDA audits are not reflective of the Company's regulatory compliance;

i) implied that criminal liability could exist with respect to nominal operations and/or non-existent safety concerns or otherwise;

j) asserted material deficiencies of safety standards with respect to x-ray or other equipment when the Company was meeting the applicable standards and there being no reason to suspect any safety failure with respect to same;

k) nor otherwise communicated any contextual conversations or reports in the nature of that presented to me by Madison.

35. The decisions to suspend Madison and later terminate her was not related, in any way to her sex or race, but merely her actions indicating she was not qualified to perform the services she was hired to do, arising out of the above noted issues with her work product.

36. Madison's Legal Analysis and oral statements were materially irreconcilable with respect to first-hand information and beliefs held by Creative Werks' management team, and the purported risk issues raised by Madison were inconsistent with Creative Werks' history, culture, understanding of regulations, and reflected a wholesale disregard for objectively verifiable data.

I declare under penalties of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) that the foregoing is true and correct.

Executed on June 9, 2025

DocuSigned by:
Steve Schroeder
AE5ED0F9A4E04CC...
(Signature)

Steve Schroeder

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 17

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

DECLARATION OF GRETCHEN LEMAY
IN SUPPORT OF MOTION FOR SUMMARY JUDGEMENT

1. I, Gretchen LeMay, have personal knowledge of all statements set forth in this Declaration, and if called to testify, will assert same under oath and under penalty of perjury.

2. I am the Head of People of Creative Werks LLC ("creative werks"), and have been employed in this position since July of 2022. In this capacity, I manage and oversee Creative Werks' human resources, which includes but not limited to hiring, terminations, disciplinary actions, and recruitment.

3. On Friday October 21, 2022, prior to Mary Madison ("Madison) speaking with Mr. Schroeder, Madison asked to speak with me, but she did not indicate the purpose of the requested meeting. I indicated, in an email, that I was not available until Monday and, in response, she agreed that she would speak with me on that day. Madison did not follow up with her request to meet with me thereafter.

4. I was involved in the decision, with others, to suspend and terminate Madison's employment.

5. Madison's termination arose out of a document that she drafted entitled "Regulatory Business Problem" (hereinafter "Legal Analysis") and an oral presentation that she made to creative werks's President, Steve Schroeder, due to its leading creative werks to determine that Madison was not qualified for her position and that she engaged in what appeared to be an intentionally misleading, un-researched, alarmist and irrational work product, in addition to failing to provide her "work product" to her supervisors prior to tendering to the PRESIDENT. I received a copy of the Legal Analysis from Steve Schroeder upon his receipt of same.

6. Based on feedback I received from others, the Legal Analysis was a poor work product, full of gross misstatements, reflecting a misunderstanding of applicable regulatory compliance requirements, consisting of false assertions of fact, lacking in research, unprofessional, reflecting a wholesale misunderstanding of creative werks' safety culture, reflecting a gross mischaracterization of events and reports at Madison's disposal and/or audit findings, and generally reflecting alarmist, non-rational, and containing several unsubstantiated conclusions. creative werk's management believed that Madison's Legal Analysis and oral statements to Schroeder, were materially irreconcilable with respect to first-hand information and beliefs held by creative werk's management team, and the purported risk issues raised by Madison were inconsistent with creative werks' history, culture, understanding of regulations, and reflected a disregard for objectively verifiable data.

7. Madison was terminated on January 17, 2023. Her termination was communicated to her lawyer, Jordan Hoffman on that date, and creative werks contemporaneously modified its records to reflect same. (See Exhibit 14 from creative werks' HR management system; see also Declaration of C. Thorstenson). Madison had never filed any legal actions against creative werks or Steve Schroeder, nor did she communicate any belief or accusation to creative werks that she was being discriminated against until after she was terminated, in a letter dated January 23, 2023.

8. The decision to suspend Madison and later terminate her was not related, in any way to her sex or race, but merely her actions indicating she was not qualified to perform the services she was hired to do, arising out of the above noted issues with her work product.

9. Due to my position as head of the human resource departments, I have knowledge and/or access to records relating to actions taken by employees that either were raised as a potential bases for disciplinary actions, and/or which resulted in disciplinary actions. Based on a review of records and my own knowledge, Erich Zicher has never been the subject of any disciplinary investigation or received any disciplinary actions from creative werks. I am not aware of Zicher ever having engaged in any unprofessional actions, nor suggesting alarmist conclusions, nor submitting any materially flawed work product, or otherwise having submitted any reports or communications to the Company and/or its PRESIDENT which caused concerns as to any lack of professionalism and/or materially flawed work product and/or allegations of potential criminal conduct/liability and/or breaches of fiduciary duty and/or suggesting that the Company does not seek to comply with regulatory schemes.

10. With respect to the documents attached to the Statement of Undisputed Fact, Exhibits 2-12, they are business records that were maintained by creative werks and:

a) They were made at or near the time of the event(s) reflected therein;

b) They were created contemporaneously with or shortly after the event recorded therein;
c) They were made in the regular course of business;

d) They were generated as part of a routine and regular business practice of creative werks;

e) It was the ordinary practice of the business to create and/or retain such records;

f) They were made by a person with knowledge or from information transmitted by a person with knowledge:

g) They were created by someone familiar with the event or based on information from someone with such knowledge, who reported it in the regular course of business; and

I declare under penalties of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) that the foregoing is true and correct.

Executed on June 9, 2025

Signed by: Gretchen LeMay DD018F8D46AF494...

(Signature)

Gretchen LeMay

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON, Plaintiff, v. CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually Defendants.	)	No. 23-cv-16476 Hon. Manish S. Shah

Exhibit 18

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

DECLARATION OF CRAIG R. THORSTENSON

1. I, CRAIG THORSTENSON, have personal knowledge of all statements set forth in this Declaration, and if called to testify, will assert same under oath and under penalty of perjury.

2. I, acted in the capacity of outside legal counsel for Creative Werks LLC in relation to Mary Madison. In that capacity, I had various communications with her legal counsel, Jordon Hoffman. On on January 17, 2023, I advised Mr. Hoffman, telephonically, that Mary Madison was terminated from Creative Werks as of that date.

3. She was also tendered a Severance Agreement reflecting that January 17, 2023 as her effective date of termination.

I declare under penalties of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date) that the foregoing is true and correct.

Executed on June 9.00, 2025

Signed by: Craig R. Thorstenson E280559E6E44433...
_____ (Signature)
CRAIG THORSTENSON